Attorney's Scket No.: 10634-005001 / UCFII 848

Applicant: Ching Song e-al. Serial No.: 10/072,128 Filed: February 8, 2002

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## **REMARKS**

Claims 1-62 are pending. Claims 3-11, 17-32, 35-42, and 48-62 are withdrawn from consideration. Claims 1 and 33 have been amended and claims 16 and 47 have been cancelled. Thus, claims 1, 2, 12-15, 33, 34, and 43-46 are pending in the application.

Applicants have introduced the following clause into both independent claims 1 and 33:

provided that when R<sup>1</sup>, R<sup>2</sup>, R<sup>4</sup>, R<sup>4</sup>, R<sup>8</sup>, R<sup>9</sup>, R<sup>11</sup>, R<sup>12</sup>, R<sup>14</sup>, R<sup>15</sup>, R<sup>16</sup>, and R<sup>17</sup> are hydrogen; R<sup>10</sup> and R<sup>13</sup> are CH<sub>3</sub>; R<sup>5</sup> and R<sup>6</sup> together are a double bond between C-5 and C-6; R<sup>7</sup> is hydrogen or oxo; R<sup>17</sup> is CH<sub>3</sub>CH(CH<sub>2</sub>)<sub>3</sub>CH(CH<sub>3</sub>)<sub>2</sub>; and n is 0, then R<sup>3</sup> is (CH<sub>3</sub>CH<sub>2</sub>)<sub>3</sub>HN<sup>(+)</sup> (-)OSO<sub>2</sub>O- or X-Y- wherein X is hydrogen, amino, carboxyl, halo, sulfonic acid, -O-sulfonic acid, or alkyl; Y is -S-, -NH-, -N(alkyl)-, -SO-, -SO<sub>2</sub>-, -O-SO<sub>2</sub>-, -SO<sub>2</sub>-O-, -CO-, -CO-NH-, -CO-N(alkyl)-, -NH-CO-, or -N(alkyl)-CO-

In other words, when  $R^1$ ,  $R^2$ ,  $R^4$ ,  $R^{4'}$ -  $R^{17}$  and  $R^{17'}$  are selected so as to correspond to the skeletal substitution pattern of cholesterol or 7-ketocholesterol, the identity of the remaining variable,  $R^3$ , must be selected from one of the substituents recited above. Accordingly,  $R^3$  can now be either the O-sulfonic acid triethylammonium salt group,  $(CH_3CH_2)_3HN^{(+)}$  (-)OSO<sub>2</sub>O-, or X-Y-. With regard to the latter option for  $R^3$ , Applicants' amendment now excludes the O-sulfonic acid group,  $HOSO_2O$ - (i.e., X=H and  $Y=SO_3O$ -) as a permissible X-Y- substituent. Support for these amendments appears throughout the specification including at page 2, lines 22-28 and page 7, lines 13-14. The specification teaches that "Salts of the compounds described above, if applicable, are also within the scope of this invention" and that salts can be formed between an acidic group and, e.g., an ammonium cation (Specification, page 2, lines 22-25). Example 3 specifically teaches the exclusive use of 7-ketocholesterol sulfate triethylammonium in a reporter gene transactivation assay (Specification, page 7, lines 13-14).

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## Rejections under 35 U.S.C. 102(b)

The Examiner has rejected claims 1,2, 12-16, 33, 34, and 43-47 as being anticipated by Bleau et al. According to the Examiner:

Bleau teach cholesterol sulfate and 7-ketocholesterol sulfate and compositions comprising said compounds and saline... (Office Action, page 3, part 6).

Bleau discloses cholesterol sulfate and 7-ketocholesterol sulfate, both of which are shown in Attachment A as structures A and B respectively. Both A and B contain the Osulfonic acid group, HOSO<sub>2</sub>O-, at the position corresponding to R<sup>3</sup> in Applicants' formula (1). Bleau discloses that the steroids and sterols are prepared as the ammonium salts, however Bleau does not describe the specific preparation of the triethylammonium salt (Bleau, page 6, Table III).

As discussed above, Applicants have amended claims 1 and 33 so that  $R^3$  cannot be the O-sulfonic acid group,  $HOSO_2O$ - (i.e., X=H and  $Y=SO_3O$ -), when  $R^1$ ,  $R^2$ ,  $R^4$ ,  $R^4$ -  $R^{17}$  and  $R^{17}$  are selected so as to correspond to the skeletal substitution pattern of cholesterol or 7-ketocholesterol. In other words, both cholesterol sulfate and 7-ketocholesterol sulfate now fall outside of the scope of claims 1 and 33 as amended.  $R^3$  can however be the sulfonic acid triethylammonium salt group, which is not described in Bleau. Therefore, Bleau does not anticipate independent claims 1 and 33 as amended.

Turning to dependent claims 2, 12-16, 34, and 43-47, Applicants have cancelled claims 16 and 47, which are drawn to 7-ketocholesterol sulfate. Since independent claims 1 and 33 are not anticipated by Bleau, then claims 2, and 12-15, which depend from claim 1, and claims 34 and 43-46, which depend from claim 33, are also not anticipated by Bleau.

## **CONCLUSION**

Applicants submit that all pending claims under consideration are in condition for allowance for the reasons set forth above and respectfully request that the rejection of these pending claims be withdrawn.

## ATTACHMENT A

cholesterol sulfate (A)

7-ketocholesterol sulfate (B)